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25. (new) The vest of claim 21, wherein the bottom-chest panel and the top-belt panel are made of nylon fabric double coated with polyurethane.

26. (new) The vest of claim 21, wherein the width of said bladder is at least two inches greater than the width of the belt.

27. (new) The vest of claim 21, wherein the width of said belt is about ten inches.

28. (new) The vest of claim 24, wherein the bottom-chest panel and the top-belt panel are made of nylon fabric double coated with polyurethane.

29. (new) The vest of claim 24, wherein the width of said bladder is at least two inches greater than the width of the belt.

30. (new) The vest of claim 24, wherein the width of said belt is about ten inches.

Remarks

Claims 6 through 8 and 12 through 20 remain pending in the application.

The Office Action rejects claims 6 through 8 and claims 12 through 20 as being obvious over Woudenberg et al., Cardiopulmonary Resuscitator, U.S. Patent 4,664,098 (May 12, 1987) for the same reasons set forth in the previous office action, paragraph 1 (the Office Action of July 5, 2001).

The previous Office Action asserted that Woudenberg shows all the structural and functional limitations of the invention but does not specify the material choice and does not show a larger bladder. The Examiner further asserted that the material choice or size are considered obvious choices of design, either known in

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the art or based on user preference to suit particular applications.

In the Response to Arguments section of the current office action, the Examiner argues that the limitation of a belt having a width covering a "substantial" portion of the chest does not set forth any metes and bounds to define belt width. The Examiner asserts that Woudenberg discloses numerical values, but that the values are not precluded from being interpreted as "substantial." The Examiner then states that there is no reason why the belt of Woudenberg could not be considered to cover a "substantial" portion of the chest, especially if the patient were smaller in stature.

With respect to the current Office Action's response to arguments, Applicants have amended claims 6, 12, 15, and 18 to specify that the belt is sized "to cover substantially the entire width of the chest between the armpits and to cover substantially the entire superior-inferior length of the sternum." Claim 15 specifies that the belt have "a width to cover the thorax of the patient." In either case, the claim language sets forth definite metes and bounds that define the size of the belt, including the belt width.

The size of the belt and the size of the bladder are not issues of design choice. Woudenberg is clear that both the belt and the bladder need to be of a certain size to be effective with his invention. Specifically, Woudenberg operates only by impingement of a small (4 inch) disk over the sternum and uses a small belt of approximately the same width (see Figure 1). Thus Woudenberg operates only over a small portion of the chest surface, as does manual CPR. (Figure 2 clearly shows that the belt and the disk are small in relation to the size of the chest.) Under classic CPR theory, compression of the sternum as shown in Woudenberg is thought to be necessary for effective inducement of blood flow. However, use of a bladder which covers and acts on

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the entire anterior surface of the chest is proving more effective. This is a surprising result and thus Applicants' claims are both novel and non-obvious.

With respect to the current Office Action's rejections, Applicants respectfully point out that the Examiner did not respond to all of Applicants' arguments. The Examiner also did not respond to the same arguments presented in the next previous Office Action (dated December 28, 2000). Specifically, the Examiner has not responded to arguments against using Woudenberg as a reference to support an obviousness rejection. Applicants respectfully request that the Examiner fully consider all of the following arguments.

The Office Action's assertion that material choice or size is an obvious design choice is not a substitute for the required analysis of patentability. The case of Graham v. John Deere Co., 383 U.S. 1 (1966), eliminates application of all such maxims in favor of the mandated test for patentability. The mere statement that, in any one person's opinion, a given element is an "obvious design choice" does not accomplish the legally required inquiry. There is no rational basis for application of such an assertion, and thus the assertion deprives the applicant of his right to have his application considered under uniform standards on par with all other applicants. Therefore the rejection should be withdrawn.

Regardless of any "design choice" issue, Woudenberg teaches away from the claims and thus the claims are non-obvious. Woudenberg discloses a 10 centimeter (4 inch) wide belt, see column 5, lines 45-52. Woudenberg specifically states that, "We have found this width of belt to be particularly suitable as it prevents substantial rocking of the mounting means, i.e. during operation of the apparatus." From this language it is easily understood that Woudenberg requires a relatively narrow belt. Thus, the width of the belt is not a "mere design choice" as asserted by the Office Action. On the other hand, claims 1, 12,

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and 18 require that the belt be sized to cover substantially the entire width of the chest between the armpits and to cover substantially the entire superior-inferior length of the sternum. Claim 15 requires that the belt have a width to cover substantially the entire thorax of the patient. These limitations take advantage of the surprising discovery that compressing the entire chest has a beneficial effect. Thus Woudenberg, which performs traditional CPR, teaches away from the claims.

In addition, Woudenberg does not show a bladder sized to cover substantially the entire chest; instead, Woudenberg shows a small (4 inch diameter) contact surface that is designed to perform manual-style CPR. On the other hand, the claims contain limitations directed to a bladder adapted to cover substantially the entire surface of the chest. This limitation, present in all of the claims, is not disclosed or hinted at by Woudenberg. Indeed, as with the belt size, Woudenberg teaches away from the claims.

In addition, in Applicant's experience a narrow belt, as taught by Woudenberg, would saw the patient's body as it performs hundreds of compressions over the course of the time required for a typical treatment. The sawing action may produce severe lacerations about the edges of the belt as the belt performs hundreds compressions over the treatment time. By using a wider belt Applicant reduces the pressure about the edges of the belt, and thus alleviates the problem of sawing. The sawing issue is not obvious and is overlooked in all of the references. Moreover, the sawing issue further demonstrates that the choice of belt is not one of design or material choice, contrary to the assertion of the Office Action.

In addition, the physical interaction between the belt, the bladder, and the body of the patient is not readily understood, insofar as it is not possible to predict the effect of various changes in components and parameters on the resultant blood flow.

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Thus, there is no motivation to make any changes to the belt or bladder shown in Woudenberg. Moreover, Woudenberg teaches the application of force over a 4 inch circular region over the xiphoid process, coincident with the point at which manual CPR is applied. It is clear that the resultant point force compression might cause cardiac compression comparable to manual CPR. Merely changing the size of the Woudenberg components will have no certain effect on the degree to which the heart is compressed. It may well have had a deleterious effect if the bladder is merely enlarged to the extent necessary to partially cover the ribs, which are less compliant than the area over the xiphoid process. Thus, the suggestion that changes in size of the components is a matter of design choice is unfounded.

Because Woudenberg teaches away from Applicants' claims and because there is no motivation to make any changes to the Woudenberg belt or bladder, Woudenberg is inapplicable as a reference to establish the obviousness of Applicants' claims. Accordingly, Applicant requests reconsideration and allowance of the claims.

Further regarding claims 8, 14, 15, 17, 18, and 20, the rejection ignores additional limitations of the claims. Claims 8, 14, 15, 17, and 20 require that the bladder be wider than the belt. The relative sizes of the belt and the bladder are not addressed in the rejection or the response to Applicants' arguments. Woudenberg provides no disclosure or hint that the bladder should be wider than the belt. On the contrary, Woudenberg's disclosure on the size of the belt and bladder, including the Figures, indicate that the bladder must be smaller than the belt. With regard to claim 18, the claim requires that the bladder be detachable from the belt. There is no motivation or suggestion present in Woudenberg to make the bladder detachable.

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Regarding new claims 21 through 30, each claim contains the limitations that the belt and the bladder "cover substantially the entire anterior surface of the chest." Thus, claims 21 through 30 are directed to a device that performs CPR by compressing substantially the entire chest (a new CPR technique). Woudenberg does not show a bladder or a belt that covers substantially the entire anterior surface of the chest. On the contrary, Woudenberg shows a small bladder and a small belt consistent with a device that performs a traditional CPR technique. Thus, Woudenberg teaches away from claims 21 through 30. Accordingly, Applicants respectfully request allowance of new claims 21 through 30.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

Date: September 9, 2002

By:



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Reg. No. 34,311

Docket No. 212/219

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of:

Rothman, et al.

Serial No.: 09/062,717

Filed: April 20, 1998

For: Belt with Detachable Bladder
for Cardiopulmonary Resuscitation
and Circulatory Assist

Art Unit: 3764

Examiner: Koo, B.

ATTACHMENT OF CLAIMS AND AMENDED SPECIFICATION PARAGRAPHS

The claims, including those amended by the Response submitted herewith on September 9, 2002, are as follows:

6. (twice amended) An inflatable vest for administering CPR to a patient, the patient having a chest, [and said chest having an anterior surface,] armpits, and a sternum, said sternum having a superior-inferior length and said chest having an anterior surface, the inflatable vest comprising:

a belt sized to circumferentially fit around the patient[, the belt having a width to cover a substantial portion of the chest of the patient] and to cover substantially the entire width of the chest between the armpits and to cover substantially the entire superior-inferior length of the sternum, said belt being substantially circumferentially inextensible when fitted around the patient; and

a bladder attached to the belt, said bladder having a width and said bladder comprising:

a bottom-chest panel composed of an inextensible material that is adapted to cover at least [a substantial]

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substantially the entire portion of the anterior surface of the chest of the patient;

a top-belt panel composed of an inextensible material and sealed to the bottom-chest panel to form a gas tight bladder chamber having an opening to receive compressed gas;

wherein the bottom-chest panel and the top-belt form a radially extensible bellows.

7. (unchanged) The vest of claim 6, wherein the bottom-chest panel and the top-belt panel are made of nylon fabric double coated with polyurethane.

8. (unchanged) The vest of claim 6, wherein the width of said bladder is at least two inches greater than the width of the belt.

12. (amended) An inflatable vest for administering CPR to a patient, the patient having a chest, armpits, and a sternum, said sternum having a superior-inferior length, the vest comprising:

a belt sized to circumferentially fit around the patient[, said belt having a width to cover a substantial portion of the chest of the patient] and to cover substantially the entire width of the chest between the armpits and to cover substantially the entire superior-inferior length of the sternum, said belt being substantially circumferentially inelastic when fitted around the patient; and

a bladder, attached to the belt, said bladder having a width, said bladder comprising:

a bottom-chest panel composed of an inelastic material that is adapted to cover at least [a substantial] substantially the entire portion of the top of the chest of the patient; and

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a top-belt panel composed of an inelastic material and sealed to said bottom-chest panel to form a gas tight bladder chamber having an opening to receive compressed gas;

wherein the bottom-chest panel and the top-chest panel form a radially inelastically extensible bellows.

13. (unchanged) The vest of claim 12, wherein the bottom-chest panel and the top-belt panel are made of nylon fabric double coated with polyurethane.

14. (amended) The vest of claim 12, wherein the width of said bladder is at least two inches greater than the width of the [vest] belt.

15. (amended) An inflatable vest for administering CPR to a patient, the patient having a thorax, the vest comprising:

a belt sized to circumferentially fit around the patient, said belt having a width to cover substantially the entire thorax of the patient, said belt being substantially circumferentially inextensible when fitted around the patient; and

a bladder, attached to the belt, said bladder having a width greater than the width of the belt, said bladder comprising:

a bottom-chest panel composed of an inextensible material that is adapted to cover substantially the entire thorax of the patient;

a top-belt panel composed of an inextensible material and sealed to said bottom-chest panel to form a gas tight bladder chamber having an opening to receive compressed gas;

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wherein the bottom-chest panel and the top-chest panel form a radially extensible bellows.

16. (amended) The vest of claim 15, wherein the width of said belt is about [(10)] ten inches.

17. (amended) The vest of claim 15, wherein the width of said bladder is at least two inches greater than the width of the [vest] belt.

18. (twice amended) An inflatable vest for administering CPR to a patient, the patient having a chest, armpits, and a sternum, said sternum having a superior-inferior length, said vest comprising:

a belt sized to circumferentially fit around the patient[, said belt having a width to cover a substantial portion of the chest of the patient] and to cover substantially the entire width of the chest between the armpits and to cover substantially the entire superior-inferior length of the sternum, said belt being substantially circumferentially inextensible when fitted around the patient;

a detachable bladder, detachably attached to the belt, said bladder having a width, said bladder comprising:

a bottom-chest panel composed of an inextensible material that is adapted to cover at least [a substantial] substantially the entire portion of the top of the chest of the patient;

a top-belt panel composed of an inextensible material and sealed to said bottom-chest panel to form a gas tight bladder chamber having a opening to receive compressed gas;

wherein the bottom-chest panel and the top-chest panel form a radially extensible bellows.

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19. (unchanged) The vest of claim 18, wherein the bottom-chest panel and the top-belt panel are made of nylon fabric double coated with polyurethane.

20. (amended) The vest of claim 18, wherein the width of said bladder is at least two inches greater than the width of the [vest] belt.

21. (new) An inflatable vest for administering CPR to a patient, the patient having a chest, said chest having an anterior surface extending laterally between the patient's armpits and superiorly along the superior-inferior length of the patient's sternum, said inflatable vest comprising:

- a belt sized to circumferentially fit around the patient's chest and to cover substantially the entire anterior surface of the chest, said belt being substantially circumferentially inextensible when fitted around the patient; and

- a bladder attached to the belt so that, when the belt is fitted around the patient's chest, the bladder is disposed between the belt and the patient's chest, said bladder having a width and said bladder comprising:

- a bottom panel composed of an inextensible material that is adapted to cover substantially the entire anterior surface of the chest of the patient;

- a top panel composed of an inextensible material and sealed to the bottom-chest panel to form the bladder.

22. (new) The vest of claim 21 wherein the bladder further comprises an opening to receive compressed gas.

23. (new) The vest of claim 21 wherein the bottom-chest panel and the top-belt form a radially extensible bellows.

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24. (new) The vest of claim 22 wherein the bottom-chest panel and the top-belt form a radially extensible bellows.

25. (new) The vest of claim 21, wherein the bottom-chest panel and the top-belt panel are made of nylon fabric double coated with polyurethane.

26. (new) The vest of claim 21, wherein the width of said bladder is at least two inches greater than the width of the belt.

27. (new) The vest of claim 21, wherein the width of said belt is about ten inches.

28. (new) The vest of claim 24, wherein the bottom-chest panel and the top-belt panel are made of nylon fabric double coated with polyurethane.

29. (new) The vest of claim 24, wherein the width of said bladder is at least two inches greater than the width of the belt.

30. (new) The vest of claim 24, wherein the width of said belt is about ten inches.

End